Title 18. Public Revenue
Sales and Use Tax Regulation, Regulation 1591, *Medicines and Medical Devices*

FINAL STATEMENT OF REASONS
Overview/Non-Controlling Summary

Update

Regulation 1591 interprets and explains the Sales and Use Tax Law as it applies to sales of medicines and medical devices. It explains the situations when sales of such property are subject to sales and use tax and when they are not.

Specific Purpose

The purpose of the proposed amendment is to interpret, implement, and make specific Revenue and Taxation Code section (Section) 6369 as it applies to such sales. This amendment is necessary to provide guidance to the taxpayers that engage in such transactions.

Factual Basis

Regulation 1591, in part, defines what tangible personal property constitutes "medicines." The Board amended the regulation to clarify the application of tax to certain sales of medical products. The amendment explains that, subject to certain qualifications, the term "medicines" includes certain items approved by the U.S. Food and Drug Administration (FDA) to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition.

The California Sales and Use Tax Law imposes either a sales or use tax on all retail sales of tangible personal property to California consumers, unless otherwise exempted by statute or type of transaction. Generally, doctors are considered consumers of products they use in performance of their medical services. The sale of these products to doctors is taxable unless the item qualifies for exemption, such as the exemption for medicines provided in Section 6369.

Section 6369, interpreted and implemented by Regulation 1591, provides that sales or other transfers of medicines as defined in the statute are not subject to tax if they are sold or otherwise transferred pursuant to the requirements set forth in the statute. In Section 6369, subdivision (b), the Legislature has provided that the term "medicines" means "any substance or preparation ***intended*** for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease and commonly recognized as a substance or preparation intended for that use [emphasis supplied]." Thus, the intent (or professional judgment) of the qualified person (e.g., doctors) ultimately prescribing or furnishing the substance or preparation for treatment is an essential element to the statutory definition of "medicines." Assuming all the other requirements for exemption are met, the

Legislature has set up a statutory scheme where the professional judgment of doctors is deferred to regarding whether they have prescribed or furnished the substance or preparation for use in the treatment of a disease. The same deference to the professional judgment of doctors and other qualified persons is also required for devices and articles (e.g., certain implants) prescribed or furnished under subdivision (c) of Section 6369.

The Board concluded an amendment was needed because Board auditors were erroneously assessing tax on sales of prescription items used to treat medical conditions. Specifically, auditors had questioned nontaxed sales of certain items that have a medical purpose when the auditors suspected that the eventual application of the specific item sold was for cosmetic purposes (i.e., for a purpose that is wholly unrelated to the treatment of a medical condition). The Board has concluded that making a determination as to whether or not an item is sold for an exempt purpose when the item is susceptible to a dual use would improperly require auditors to investigate doctors' practices and question their professional judgment and would require auditors to examine patient records in derogation of the doctor-patient privilege.

Subdivision (a)(9) – new subdivision (a)(9)(A) added to clarify that certain items approved by the FDA to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition are considered a medicine, except for items excluded from the term "medicines" in subdivision (c); former language of subdivision (a)(9) transferred to new subdivision (a)(9)(B) with word "any" capitalized accordingly. Subdivision (b), first sentence – phrase "In addition to the definition set forth in subdivision (a)(9) of this section," added to clarify that the definition of "medicines" in subdivision (a)(9) is in addition to the definitions of "medicines" contained in subdivision (b), with word "the" in the following clause not capitalized accordingly.

Local Mandate Determination

The Board of Equalization has determined that the amended regulation does not impose a mandate on local agencies or school districts.

Response to Public Comment

On April 18, 2006, the Board held a public hearing on the proposed amendment to Regulation 1591. Board staff had been in consultation with the interested parties regarding the possibility that the language of the amendment might inadvertently suggest a broader application than intended or permitted under law. In response to the March 3, 2006, Notice of Proposed Regulatory Action for the April 18, 2006, public hearing, Mr. John R. Valencia of the law firm Wilke, Fleury, Hoffelt, Gould & Birney, LLP submitted a letter dated April 12, 2006, to Ms. Diane Olson of the Board's Board Proceedings Division. Mr. Valencia's letter was specifically written on behalf of the parties that initially petitioned the Board to amend Regulation 1591 in a petition dated September 21, 2005: namely, the California Society of Dermatology and Dermotologic Surgery, the California Society of Plastic Surgery, the California Academy of Ophthalmology and the California Medical Association (hereafter, collectively, petitioners). Mr. Valencia's letter correctly stated that petitioners, other interested parties, and Board staff had reached a consensus on additional language that would further clarify the intent and scope of the amendment. The additional language clarified that, for purposes of new

subdivision (a)(9)(A), when all applicable requirements are met, the only FDA-approved items that are to be considered medicines are (1) products fully implanted or injected in the human body, (2) drugs and (3) biologics. Furthermore, Mr. Valenica, representing petitioners, spoke in support of this additional language at the public hearing. The following individuals also spoke in support of the additional language at the public hearing: Messrs. Tim Madden and Jim Randlett, representing the California Society of Plastic Surgeons; and Glenn Bystrom of the accountancy firm of Ernst & Young LLP. Staff also concurred at the public hearing that the additional language should be included. No other written or oral comments were submitted in anticipation of or at the public hearing.

The Board accepted the joint recommendation of petitioners, other interested parties and Board staff and approved the requested changes, referring the regulation to the 15-day file. The Notice to Interested Parties was issued on April 28, 2006. In response to the Notice to Interested Parties, no written or oral comments were received. The Board considered the changed version of the regulation at the Rulemaking Calendar on May 17, 2006. No written comments were received, and no oral presentations were made. The Board thereupon adopted the changed version on the regulation.

Small Business Impact

The Board of Equalization has determined that the amended regulation will not have a significant adverse economic impact on small businesses.

Adverse Economic Impact on Private Persons/Businesses Not Including Small Business

No impact.

Federal Regulations

Regulation 1591 and the proposed change have no comparable federal regulations.

Alternatives Considered

By its motion, the Board determined no alternative to amending the regulation would be more effective in carrying out the purpose for which the regulation is proposed or would be as effective and less burdensome to affected private persons than the adopted regulation.